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09/919,585	07/30/2001	Tian-Qiang Sun	PP-16093.002	2590

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EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	8

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/919,585	Applicant(s) SUN ET AL.	
	Examiner Richard G Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-25 are at issue and are present for examination.

Election/Restrictions

Applicant's election without traverse of Group I and Group B, SEQ ID NO: 4/6, Claims 1-6, in Paper No. 7 is acknowledged.

Claims 7-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

Applicants statement on the first line of the specification to state that this application claims the priority of U.S. Provisional Application Number 60/221,860, filed July 28, 2000 where this provisional application is incorporated by reference is acknowledged.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosure, paper no. 4, filed 1/10/2002, is acknowledged. Those references considered have been initialed.

Claim Objections

Claims 1-6 are objected to because of the following informalities:

Claims 1 (2-6 dependent from) contains non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (2-6 dependent on) is indefinite in that it is vague and confusing in the recitation in part (c) "...amino acids from about 1 to about 691 of SEQ ID NO: 6" and in part (d) "...amino acids from about 1 to about 691 of SEQ ID NO: 6". Specifically the use of "about" when referring to an amino acid position is vague and indefinite. What is applicants intent in reference to about 1 or about 2, and are they different? It is suggested that the word "about" be deleted from the above recitations.

Claim 1 (2-6 dependent on) is indefinite in that it is vague and confusing in the recitation in part (s) "...except for a conversion of a conserved lysine to an alanine at an

ATP binding site of the encoded amino acid sequence" . It is vague and unclear what applicants consider to be an ATP binding site of the sequences of (c) and (d) (i.e. SEQ ID NO: 6).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6 are directed to all possible nucleic acid molecules comprising any polynucleotide having (comprising) a sequence having a mere 50, 100 or 500 contiguous nucleotides from the coding region of SEQ ID NO: 4 (part k, o and p); any polynucleotide having (comprising) sequences having at least 90% identity to the above (k) or to a sequence encoding amino acids 1-691 of SEQ ID NO: 6; and sequences of (c) except at least one amino acid substitution in the encoded amino acid sequence; and vectors and host cells comprising said nucleic acid molecules and methods of making said vectors and host cells.

The specification, however, only provides the representative species of SEQ ID NO: 4, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also

fails to describe additional representative species of these nucleic acid molecules by any identifying structural characteristics or properties other than the defined relationship to SEQ ID NO: 4 or 6, for which limited predictability is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Applicant is advised to in addition to more structural detail, adding functional language to the rejected claims such that an adequate structure to function/activity relationship of the claimed genus is described.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising a polynucleotide sequence encoding SEQ ID NO: 6, does not reasonably provide enablement for any nucleic acid molecule comprising a polynucleotide sequence at least 90% identical to a sequence encoding SEQ ID NO: 6, or sequence that is a mere 50, 100 or 500 contiguous nucleotides of the coding region of SEQ ID NO: 4, or any sequence except for at least one amino acid substitution in the encoded amino acid sequence. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-6 are so broad as to encompass any nucleic acid molecule comprising any polynucleotide having (comprising) a sequence having a mere 50, 100 or 500 contiguous nucleotides from the coding region of SEQ ID NO: 4 (claim 1, part k, o and p); any polynucleotide having (comprising) sequences having at least 90% identity to the above (claim 1, part n) or to a sequence encoding amino acids 1-691 of SEQ ID NO: 6; and sequences of (c) except at least one amino acid substitution in the encoded amino acid sequence (claim 1, part r); and vectors and host cells comprising said nucleic acid molecules and methods of making said vectors and host cells.. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid molecules broadly encompassed by the claims, including all nucleic acid molecule comprising a polynucleotide sequence at least 90% identical to a mere 50 contiguous nucleotides of a sequence encoding SEQ ID NO: 6,. The claims rejected under this section of U.S.C. 112, first paragraph,

do not place minor structural limits on the claimed nucleic acid molecules such that adequate guidance is not disclosed with respect to how to make and use the majority of the scope of the claimed genus. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and thus its encoding nucleic acid's sequence and obtain the desired function or activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to that nucleic acid molecule comprising a polynucleotide sequence encoding SEQ ID NO: 6.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's or polynucleotide's sequence where modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any nucleic acid molecule comprising a polynucleotide sequence at least 90% identical to a sequence encoding SEQ ID NO: 6,

or sequence that is a mere 50, 100 or 500 contiguous nucleotides of the coding region of SEQ ID NO: 4, because the specification does not establish: (A) regions of the protein and thus polynucleotide structure which may be modified without effecting its activity; (B) the general tolerance of serine/threonine protein kinases and their encoding polynucleotides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a serine/threonine protein kinases with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain a function/activity of the claimed polynucleotides or their encoded polypeptides and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at and use the majority of those polynucleotides of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any polynucleotide encoding SEQ ID NO: 6. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24

(CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Espinosa et al., (Human serine/threonine protein kinase EMK1: genomic structure and cDNA cloning of isoforms produced by alternative splicing, Cytogenet. Cell Genet., Vol 81, No 3/4, pages 278-282, 1998, Ref V, enclosed 892) as evidenced by Espinosa et al. (Genbank Accession Number X97630, October 1998).

Espinosa et al. teach isolation and cloning of a polynucleotide that encodes two isoforms of the human serine/threonine protein kinase EMK1 and Espinosa et al. teach vectors and host cells comprising said polynucleotide and methods of making said vectors and host cells. The polynucleotide isolated, cloned and disclosed by Espinosa et al. has a best local similarity score of greater then 92% when compared to the sequence of SEQ ID NO: 4 and the taught nucleic acid comprises polynucleotide

sequences of at least 500 contiguous nucleotides of the coding region of SEQ ID NO: 4, as evidenced by Espinosa et al. (Genbank Accession Number X97630, October 1998).

Therefore, Espinosa et al. anticipates claims 1-6.

Remarks

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson, Ph.D.
Primary Patent Examiner
Art Unit 1652
May 2, 2003